WSA 2004 Proposed Project

Project Name:	Market Surveillance (N01479)
Purpose:	Plan and implement a market surveillance program to collect, analyze, and disseminate information regarding products manufactured by PM USA .

Reason for Doing this Work:

- ☒ Guidance
- ☐ Evaluation
- ☐ Product Design
- ☐ Short Term
- ☒ Long Term

Initiative and sub-initiative: (Check all areas that apply)

- ☐ Determinants of Exposure
  - ☐ Addiction
  - ☐ Ammonia
- ☐ Understanding Product Toxicity vs Product Design
  - ☐ Exposure
  - ☐ Carbon
  - ☐ Menthol
  - ☐ Low Tar
  - ☐ ETS
  - ☐ Specific Compounds
- ☐ Evaluation Framework Clinical
  - ☐ Cancer
  - ☐ COPD
  - ☐ CVD
  - ☐ Molecular Biology
  - ☐ All Disease
- ☐ Evaluation Framework Non-Clinical
  - ☐ Cancer
  - ☐ COPD
  - ☐ CVD
  - ☐ Molecular Biology
  - ☐ All Disease
- ☐ Broaden Flexibility after Clinical Studies
- ☐ Rapid Screening
- ☐ Knowledge Management
- ☐ Risk Assessment
- ☒ Communication
- ☒ Surveillance
- ☐ Smoking Conditions
- ☐ Improve Prep Subjectives
- ☐ Lit End Cigarette Reduced Exposure Design

Project Leader:	Candace Adams
Functional Area:	Clinical Evaluation
Prioritization:	☐ Critical ☒ Priority ☐ Secondary ☐ Low

Milestones:	**Target Start Date:**	**Target Completion Date:**
Establish objectives		Completed
Create strategy to implement surveillance program		Completed
Document strategy/guidelines		Completed
Recruit participants (Pilot Study)	01/01/ 2004	12/31/ 2004
Conduct pilot study	1st Quarter 2004	March 2005
Recruit additional participants (Ongoing study)	01/01/ 2005	Open end
Data collection	April 2005	Open end
Data analysis	06/30/2004	Open end
Yearly Reporting	Ongoing	Open end

Internal Resource Allocation (WSA, PMRL, PMI) (Man Hours)	**External Resource Allocation (other PMUSA, external vendors)** (Man Hours)
C. Adams – 700; A. Hayden 1,000 hrs	Guardiant LLC and a company to recruit participants (bidding process initiated)

TO BE FILLED OUT BY WSA MANAGEMENT

- ☐ Approved as Written
- ☐ Approved with Modifications
- ☐ Not Approved

Signature of Project Leader's Functional Director (Date)

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Source: https://www.industrydocuments.ucsf.edu/docs/gmlj0001